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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,244

11/13/2003

Whye-Kei Lye

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09/13/2006

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,244

Applicant(s)

LYE ET AL.

Examiner

DAVID J. ISABELLA

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3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/05;1/06;5/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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Election/Restrictions

Applicant's election without traverse of Group I claims 1-9, 11-14, and 16-22, drawn to a method of fabricating an implantable medical device in the reply filed on 7/7/2006 is acknowledged. Applicant further elected the species directed to cobalt chromium.

Claims 10,15,23-41 have been cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleming [3190749].

A method of fabricating a metal substrate including providing at least one alloy and removing at least one component of the alloy to form at least one porous layer is fully disclosed by Fleming.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9,11-14,16-18,21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertner et al [WO 03/045582 or US2005/0106212] in view of Fleming [3190749] or Sieradzki et al [4977038].

Gertner et al discloses a method for forming a stent including micro-pitting the surface of the stent for receipt of bioactive agents. The micro-pitting is performed by etching. Each of Fleming and Sieradzki et al teach forming porous metallic substrate by removing certain alloyed portions creating a porous matrix. To form the porous surface of Gertner by a dissolution of salt or predetermined alloyed portions from the metallic alloy would have been obvious from the teachings of either of Fleming or Sieradzki et al to provide a non-corrosive surface which would reduce unwanted leachings of metallic ions in vivo.

Claims 3 and 9, see paragraph [0038] of Gertner et al.

Claims 4 and 5, see paragraph [0005] of Gertner,et al.

Claims 6-8, the body and therefor the exposed surfaces of the stent comprises the alloy.

Claims 11 and 12, see teachings in columns 1 and 2 of Fleming,

Claim 13, if the alloy, cobalt-chromium, contains impurities eg. aluminum, then it is well known in the art to remove the aluminum by leaching the alloy in a bath of sodium hydroxide. (See for example Baldi [6093498]).

Claim 14, see secondary references to either of Fleming or Sieradzki et al.

]Claims 16-18, see Gertner et al.

Claims 21 and 22, see Gertner et al as modified by Fleming or Sieradzki et al supra.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gertner et al [WO 03/045582 or US2005/0106212] in view of Fleming [3190749] or Sieradzki et al [4977038] as applied to claim 1 above, and further in view of MacGregor [4459252].

A vascular prosthesis having a plurality of layers and porosities is taught by MacGregor. Though it is not clear if Gertner, et al discloses the method for forming a metallic substrate having a plurality of porous layers, such concept for providing fluid communication with the surface pores to promote new tissue growth and flow of nutrients is clearly taught by MacGregor.

The porous surface intended to engage blood must have an interconnected network of pores beneath the surface in fluid flow communication with the surface 10 pores to promote the colonization by nucleated cells and subsequent differentiation into other cell types so that the tissue which is formed and grows into the surface is interlocked in the subsurface network rendering the surface non-thrombogenic. The network of pores 15 preferably extends substantially throughout the body of the porous system.

The interstitial pore size may vary widely, generally from about 1 micron up to about 1000 microns, although it may be preferred to use pore sizes below 20 about 20 microns. The porosity also may vary widely, generally from about 8% by volume to the limit of coherence of the porous surface, and usually in the range of about 10 to about 50% by volume.

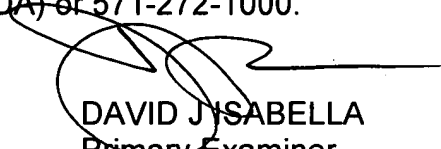
The porous surface may be provided as part of a 25 composite of a porous coating embodying the surface on a coherent substrate in certain embodiments of the invention, although a wholly porous structure may be used. The thickness of the porous coating may vary from double layers of particles upwards, generally from 30 about 1 to about 10,000 microns, thin layers being preferred in devices having close tolerances.

To provide more than one porous layer to the device of Gertner et al to promote new tissue formation would have been obvious from the teachings of MacGregor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
9/6/2006